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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,526	01/16/2004	Frank R. George	66672-019	7037

41552 7590 05/04/2009

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EXAMINER	
EPPS SMITH, JANET L	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
05/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP_Docket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/759,526	GEORGE ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-15,17-28,63-76,85 and 86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-15,17-28,63-76,85 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-15, 17-28, 63-76, 85 and 86 are presently pending for examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-3, 5-15, 17-28, 63-76, 85 and 86 stand under 35 U.S.C. 112, first paragraph, is withdrawn in response to Applicant's arguments.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1-3, 5-7, 9-15, 17-22, 24-28, 63-69 under 35 USC 102(b) is withdrawn in response to Applicant's amendment to remove the limitation "synovium" from the claims.

5. Claims 8, 23, and 70 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (US 4758429).

6. Applicant's arguments filed 2-29-06 have been fully considered but they are not persuasive. Applicants traversed the instant rejection on the grounds that the rejection is moot by the amendments to the claims proposed above.

7. Contrary to Applicant's assertions since the instantly rejected claims have not been amended to remove all cells that are found within synovial tissue, the instant claims remain rejected for the reasons of record.

8. For example the instant claims recite wherein the treated cell is selected from the following group consisting of fibroblast, neuronal cell, epithelial cell, macrophage,

neutrophil, keratinocyte, endothelial cell, epidermal melanocyte, hair follicle papilla cell, skeletal muscle cell, smooth muscle cell, osteoblast, neuron, chondrocyte, hepatocyte, pancreatic cell, kidney cell, aortic cell, bronchial cell and tracheal cell.

9. Absent evidence to the contrary, to the extent that macrophage cells, fibroblast, chondrocytes, osteoblast, and etc. are found in synovial tissue. The instant claims remain rejected for the reasons of record. As stated in the prior Office Action Gordon teaches a method for the treatment of arthritis and joint diseases comprising delivering a sufficient amount of electromagnetic energy to inflammatory diseased cells in the joint and joint space, see col. 2, lines 20-35, and col. 9, see Example II.

10. Since the methods of Gordon et al. teach the delivery of an effective amount of electromagnetic energy to joint cells, which comprise synovial tissue, absent evidence to the contrary, the methods of Gordon inherently function for accelerating the cell cycle of a cell, which results in an increase in DNA replication and the shortening of the G1 stage of the treated cells.

11. Gordon further teaches that the application of the localized static magnetic or electric field may occur concurrently with the application of an alternating, oscillating or pulsed electromagnetic field. That is to say, the localized static magnetic or electric field may be superimposed on the subject of interest while the alternating, oscillating or pulsed field is also being applied. Gordon also teaches that the alternating electromagnetic field be applied at a radiofrequency of 1 to about 500 Hz, 1 Hz to 100 Hz, and a specific example of 500 Hz, for a period of approximately 10-20 minutes, and repeated as necessary.

Claim Rejections - 35 USC § 112

12. The rejection of claims 10-14 and 71-76 is withdrawn in response to Applicant's amendment to the claims.

13. Claim 9 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Applicant's arguments filed 2-09-09 have been fully considered but they are not persuasive. Applicants traversed the instant rejection is moot in view of Applicant's amendment to claims 9-14 and 71-76. However, since Applicants did not amend claim 9, this claim remains rejected for the reasons of record.

15. As stated in the prior Office Action claim 9 recites "further comprising delivering to said cell an effective amount of electromagnetic energy to..." This additional step is unclear since it is not apparent that two separate doses of electromagnetic energy is to be delivered to the cells, or if Applicants are further defining the effects of delivering the first dose of electromagnetic energy to the treated cells.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. Claims 1-3, 5-15, 17-28, 63-76 and 85-86 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Ganz et al. (US 6491618; see entire disclosure of reference).

18. Ganz et al. teach a method and means for directing light radiation onto the lining of a body cavity for the treatment of a gastrointestinal ailment of a patient. The body cavity of the patient is then irradiated with ultraviolet light radiation in a preferred range of about 250 nm to 270 nm so as to kill or debilitate microorganisms lining the body cavity without serious destruction of the body tissue of the patient to thereby improve or alleviate one or more of the symptoms of the gastrointestinal ailment. (see abstract)

19. Ganz et al. also teach that the methods of their invention can be used as an effective treatment for debilitating or killing microorganisms with as little intrusion as possible in other body cavities, such as the bowel, lungs, peritoneal cavity or urinary tract. (see background of the invention).

20. The radiation energy used in the methods of Ganz et al. also include wherein the radiant energy includes, e.g., x-ray, ultraviolet light, beta radiation, gamma radiation, radio waves, microwaves, or infrared energy and wherein the energy is transferred from the head of the instrument to the epithelium around the head of the instrument in an amount sufficient to debilitate or kill microorganisms in the lining of the body cavity (see summary of the invention).

21. Since the teachings of Ganz et al. discloses the method step of the claimed invention, which comprises delivering electromagnetic radiation (including light, x-ray, radiofrequency radiation, infrared, microwave and ultraviolet radiation) into a body cavity of a patient, including the gastrointestinal tract and lungs, absent evidence to the contrary the ordinary skilled artisan would also expect that the prior art method would also produce the further function of accelerating the cell cycle, activating a cell cycle regulator, activating a signal transduction protein, activating a transcription factor, a DNA synthesis protein, a receptor and inhibiting an angiotensin receptor of the cells exposed to the radiant energy.

22. Moreover, the recitation of the limitations “for” accelerating the cell cycle, activating a cell cycle regulator, activating a signal transduction protein, activating a transcription factor, a DNA synthesis protein, a receptor and inhibiting an angiotensin

receptor, recited in the preamble of the instant claims are interpreted as intended use limitations. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

23. See MPEP 2112 [R-3]:

Requirements of Rejection Based on Inherency; Burden of Proof

The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir.1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use,

new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Therefore, since the prior art teaches the method step recited in the instant claimed methods, absent evidence to the contrary, the method disclosed in the prior art would inherently produce the same result as recited in the instant claims.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633